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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,850	11/29/2001	Brian P. Brockway	349.033US3	6258

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	09/997,850	BROCKWAY ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-64,66-69,72-76,78-81 and 83-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *91-96* is/are allowed.

6)☒ Claim(s) *75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72, 87, and 99-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 72 and 87 recite that the pressure transmitting catheter is 2mm to 4 cm long. In addition, claims 100 and 103 give the range as 1-4 cm. However, there is no support for these ranges in the specification. Rather, applicant gives examples that include 2mm and 4 cm, but not the entire range. In order to claim a range, it must have textual support in the specification (see MPEP 2163.05 III). As such, this amendment introduces new matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57, 59, 61-64, 66-68 and 105-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al 3893451 in view of Brockway et al 4,846,191. Durand et al has a pressure transmitting catheter having a lumen entirely filled with a pressure transmitting liquid. The transmitting catheter of Durand et al includes a first layer of material 1 made of a plastic surrounding the lumen, and a second material 4 of metal, having a differing hardness surrounding the first layer of material. Durand teaches that one end of the catheter connects to a pressure measuring catheter via connector 2, and that the second end connects to an instrument for measuring pressure. It does not have an implantable monitor housing the transducer and the signal processing equipment. However, Brockway teaches using such an implantable housing with a wireless connection to an external monitor, for several reasons, including to avoid the risk on infection that catheter passing through the skin impose (see background section in general, with specific reference to the discussion in the first paragraph of column 2). Hence, it would have been obvious to modify Durand to use such an implantable transducer housing, so as to overcome the problems with catheters discussed in Brockway. With respect to claims 59 and 64, Brockway teaches an alternative pressure transmitting medium comprised of a gel and a fluid combination. Hence, it would have been obvious to modify Durand et al to use this medium, as it is merely the substitution of one known medium for another. With respect to claims 61, 62, 67, and 68, the combined device teaches wirelessly transmitting the data to a remote location away from the patient. With respect to claim 63, the device can be used to measure the pressures listed. In addition, with respect to claims 105-110, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem is for a particular purpose. As such, it would have been a mere

matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view Brockway et al 4846191, as applied to claims 57, 59, 61-64, 66-68,, and 105-110 above, further in view of Iwata et al 6019728. Durand et al uses a pressure transmitting liquid as the pressure transmitting medium. Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify the above combination to use a gel, to simplify the overall design.

Claims 69, 72, 99-101, and 111-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view Pohndorf et al 5,353,800. Durand teaches that the pressure transmitting catheter may connect to a measuring instrument having a transducer. Pohndorf et al shows a device where the pressure transmitting catheter connects to a transducer, which in turn has a wire extending through a catheter to an implanted medical device, which includes a signal processing device. Such an arrangement allows the wires to be protected from the external environment and allows for improved measurement, as the transducer is located close to the measurement site. Hence, it would have been obvious to modify Durand to use such a configuration, as it is merely the use of a well known configuration in the art and to improve measurement accuracy. Claims 72 and 99-101 are rejected in that the needle of Pohndorf, e.g. the PTC, is one inch long, which is in the claims range and is approximately 1.5 cm. In addition, with respect to claims 111-113, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem

is for a particular purpose. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 73, 74, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand in view of Pohndorf et al as applied to claims 69, 72, 99-101, and 111-113 above, and further in view of Brockway 4846191. With respect to claims 73 and 74, Brockway teaches an alternative pressure transmitting medium comprised of a gel and a fluid combination. Hence, it would have been obvious to modify the Durand/Pohndorf combination to use this medium, as it is merely the substitution of one known medium for another. In addition, with respect to claims 78 and 79, it would have been obvious to modify the above combination locate the transducer in an internal housing and to transmit the data out of the body, for the reasons discussed in the rejection to claim 57 above. With respect to claim 80, the Durand/Pohndorf combination teaches that it can use an implantable medical device remote from the transducer.

Claims 81, 83, 84, 96-98, and 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Brockway et al 4846191 and Iwata 6019728. Durand et al uses a saline solution as the pressure transmitting medium, in addition to the features of the taught by Durand and Brockway above, Iwata et al uses a gel as the pressure transmitting medium to fill the entire catheter. From this teaching, it would have been obvious to modify the above combination to use a gel, to simplify the overall design. In addition, with respect to claims 114-116, applicant has not stated that the type of material used for the two layers of the durometer solves a stated problem is for a

particular purpose. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for layers 3 and 4, particularly since it appears that any material would function equally as well as any other.

Claims 85, 87, 89, 90, and 102-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durand et al in view of Brockway and Iwata, as applied to claims 81, 83, 84, 96-98 and 114-116 above, further in view of Pohndorf et al. Durand teaches that the pressure transmitting catheter may connect to a measuring instrument of a transducer. Pohndorf et al shows a device where the pressure transmitting catheter connects to a transducer, which in turn has a wire extending through a catheter to an implanted medical device, which includes a signal processing device. Such an arrangement allows the wires to be protected from the external environment. Hence, it would have been obvious to modify the above combination to use such a configuration, as it is merely the use of a well known configuration in the art. With respect to claims 87 and 102-104, the needle of Pohndorf, e.g. the PTC, is one inch long, which is in the claims range and is approximately 1.5 cm. As such, it would have been obvious to make the device of the combination of the same size, as it is merely the substitution of one known catheter size for another.

Claim 75 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 91-95 are allowable.

Claims 75 and 91-95 define over the art of record in that none of the art has the slidable plug, as claimed.

Applicant's arguments filed 4/19/2004 have been fully considered but they are not persuasive.

Applicant has asserted that there is no motivation o combine Durand and Brockway. The examiner reminds applicant that the motivation to combine need not be explicit in the references. Nevertheless, the examiner points applicant to the discussion on page 2.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is

(703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
July 21, 2004

ROBERT L. NASSER
PRIMARY EXAMINER